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Registration Decision RD2013-11

Bacillus subtilis var. *amyloliquefaciens* Strain FZB24

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Registration Decision for Taegro Technical

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Taegro Technical and Taegro, containing the technical grade active ingredient *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24, to suppress fusarium wilt on greenhouse cyclamen, fusarium head blight on wheat, bottom rot on lettuce, and late blight on tomato.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] PRD2012-32, *Bacillus subtilis var. amyloliquefaciens Strain FZB24*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-32. This decision is consistent with the proposed registration decision stated in PRD2012-32.

For more details on the information presented in this Registration Decision, please refer to PRD2012-32, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Taegro Technical?

Taegro Technical contains the active ingredient *Bacillus subtilis* var. *amyloliquefaciens* strain FZB, which is a bacterium that is used as a microbial pest control agent to suppress soil-borne diseases by *Fusarium* spp., *Rhizoctonia* spp. and *Phytophthora* spp. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 acts as a plant growth promoter and also produces various antifungal agents and enzymes. Strain FZB24 of *B. subtilis* var. *amyloliqufaciens* was originally isolated from soil in Germany.

The end-use product Taegro contains *B. subtilis* var. *amyloliquefaciens* strain FZB24 as the active ingredient. Taegro is registered for use as a commercial-class biological fungicide to suppress bottom rot on lettuce (greenhouse and field), late blight on tomato (greenhouse and field), *Fusarium* wilt on greenhouse cyclamen, and *Fusarium* head blight on wheat.

Health Considerations

Can Approved Uses of *B. subtilis* var. *amyloliquefaciens* Strain FZB24 Affect Human Health?

***Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is unlikely to affect your health when Taegro is used according to the label directions.**

People could be exposed to *B. subtilis* var. *amyloliquefaciens* strain FZB24 when handling and applying Taegro. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When spores of *B. subtilis* var. *amyloliquefaciens* strain FZB24 were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based maximum residue limits to ensure that the food Canadians eat is safe.

Bacillus subtilis var. *amyloliquefaciens*, the active ingredient in Taegro Technical and Taegro, is a ubiquitous bacterium that is commonly found in soil. When *B. subtilis* var. *amyloliquefaciens* strain FZB24 was administered orally to rats, no signs of toxicity or disease were observed, and no metabolites of toxicological significance have been shown to be produced by this strain of *B. subtilis* var. *amyloliquefaciens*. Although some strains of *B. subtilis* have been isolated from food samples implicated in food poisoning, these strains demonstrated the ability to produce a highly heat-stable toxin that may be similar to a toxin produced by *Bacillus cereus*, a known food-borne pathogenic microorganism. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is not reported to produce this toxin. Also, no such effects were reported for this microorganism in the United States where it has been registered since 2000. Therefore, the establishment of a maximum residue limit is not required for *B. subtilis* var. *amyloliquefaciens* strain FZB24. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling Taegro

Occupational risks are not of concern when Taegro is used according to label directions, which include protective measures.

Workers handling Taegro can come into direct contact with *B. subtilis* var. *amyloliquefaciens* strain FZB24 on the skin, in the eyes or by inhalation. For this reason, the product label will specify that workers exposed to the end-use product must wear waterproof gloves, long-sleeved shirts, long pants, goggles, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Taegro Is Introduced Into the Environment?

Environmental risks are not of concern.

Information on the environmental fate of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 suggests that, as a soil microorganism, it is likely that *B. subtilis* var. *amyloliquefaciens* strain FZB24 could survive in soil at elevated levels under suitable environmental conditions (i.e., type of soil, moisture, acidity levels, and temperature). However, the populations of *B. subtilis* var. *amyloliquefaciens* strain FZB24 should return to naturally occurring levels over time.

Studies were conducted to determine the effects of *B. subtilis* var. *amyloliquefaciens* strain FZB24 on birds, fish, bees, aquatic arthropods, terrestrial non-arthropod invertebrates and algae. These studies showed that *B. subtilis* var. *amyloliquefaciens* strain FZB24 was not toxic or pathogenic to birds, fish, bees, aquatic arthropods, and terrestrial non-arthropod invertebrates. Adverse effects to the growth of algae were observed, however, these observations were attributed to physical properties of the bacterial suspension rather than toxicity, i.e., test suspensions were opaque which reduced photosynthesis.

In published literature, other strains of *B. subtilis* have been reported to cause infections in mammals, terrestrial insects and plants; however, these reports were few in number considering the large amount of published literature on this microorganism. Furthermore, these reports involved unusual strains, or select strains, of *B. subtilis* for which their ability to cause disease was not thoroughly investigated. There are no reports with *B. subtilis* var. *amyloliquefaciens* strain FZB24 in non-target organisms except for the intended pest.

Value Considerations

What Is the Value of Taegro?

Taegro is a non-conventional fungicide that provides suppression of tomato late blight and lettuce bottom rot as well as partial suppression of fusarium wilt on cyclamen and fusarium head blight on wheat. Taegro represents an alternative mode of action to conventional fungicides and poses a low risk of resistance development.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Taegro to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Individuals exposed to large quantities of Taegro could possibly, upon repeated exposure to the product, develop respiratory and dermal sensitivity since Taegro has been identified as a sensitizer. Therefore, anyone handling or applying Taegro must wear waterproof gloves, long-sleeved shirts, long pants, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), and shoes plus socks. Due to the irritation potential identified for Taegro, workers and handlers are also required to wear eye goggles. Also, the signal words, "POTENTIAL SENSITIZER" and "WARNING-EYE and SKIN IRRITANT" on the principal display panel and precautionary statements, "DO NOT get in eyes or on skin" and "May cause sensitization"are required on the secondary display panel of the label.

Environment

The end-use product (Taegro) label will include environmental precaution statements that prevent the contamination of aquatic systems from it use.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-32, *Proposed Registration Decision Bacillus subtilis var. amyloliquefaciens Strain FZB24*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.